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D E C I S I O N
of 27 December 2004

Case Number: T 1057/01 - 3.2.2

Application Number: 97101410.5

Publication Number: 0783869

IPC: A61B 6/00

Language of the proceedings: EN

Title of invention:
Automated determination and analysis of bone morphology

Applicant:
LUNAR CORPORATION

Opponent:
-

Headword:
-

Relevant legal provisions:
EPC Art. 52(1), 56, 84

Keyword:
"Inventive step (yes), clarity - yes (after amendment)"

Decisions cited:
-

Catchword:
-

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Case Number: T 1057/01 - 3.2.2

D E C I S I O N
of the Technical Board of Appeal 3.2.2
of 27 December 2004

Appellant: LUNAR CORPORATION
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Decision under appeal: **Decision of the Examining Division of the European Patent Office posted 5 July 2001 refusing European application No. 97101410.5 pursuant to Article 97(1) EPC.**

Composition of the Board:

Chairman: T. K. H. Kriner
Members: S. S. Chowdhury
U. J. Tronser

Summary of Facts and Submissions

I. This appeal is against the decision of the examining division dated 5 July 2001 to refuse European patent application No. 97 101 410.5.

The ground of refusal was that claim 1 of the main request was objectionable under Articles 84 and 123(2) EPC, and claims 9 to 14 were objectionable under Article 52(4) EPC. Claim 1 of the auxiliary request was objectionable under Articles 52(1) and 56 EPC. The Board has considered the following documents (of which only D1 to D3 were cited in the impugned decision):

D1: US-A-4 811 373

D2: WO-A-88/08688

D3: Smith-Bindman R. et al., "A Comparison of Morphometric Definitions of Vertebral Fracture", Journal of Bone and Mineral Research, Vol. 6, No. 1, pages 25 to 34 (1991)

D5: J. A. Kanis, et al. Osteoporosis Int. 1:182-188 (1991)

D6: Nelson, et at., "Measurement of Vertebral Area on Spine X-rays in Osteoporosis: Reliability of Digitizing Techniques", J. Bone and Mineral Res., Vol. 5, No. 7:707-716 (1990).

II. On 17 July 2001 the appellant (applicant) lodged an appeal against the decision and paid the prescribed fee

on the same date. On 16 August 2001 a statement of grounds of appeal was filed.

III. The appellant requests that the decision under appeal be set aside and that a patent be granted on the basis of the following documents:

– Description pages 1 to 3 and 5 to 32 as originally filed

– Description page 4 as filed with the letter dated 31 October 2000

– Description pages 4a and 4b as filed with the telefax dated 15 December 2004

– Claims 1 to 8 filed as filed with the telefax dated 15 December 2004

– Figures 1 to 11 as originally filed.

IV. Claim 1 reads as follows:

"A digital x-ray bone densitometer for projection scanning of the vertebra of an animal or human to obtain information about the character of a vertebra being derived from a first and second matrix of discrete data elements each having a value wherein each said data element corresponds to a defined location in said vertebra, and wherein the value of each data element is related to a physical characteristic of the material of the vertebra, the densitometer comprising: a means (14) for positioning a radiation source (12) and detector (13) in opposed relationship about a

vertebra for directing radiation along an axis (24) through the vertebra and detecting its attenuation to produce the first and second matrix of data elements; and a positioning means (14) for rotating the axis (24) between an anterior/posterior direction and a lateral direction about said vertebra so that said first matrix of discrete data elements is acquired at the anterior/posterior direction and said second matrix of discrete data elements is acquired at the lateral direction; a digital computer (18) for the following: 1) for receiving and analyzing said first matrix of data elements to determine bone mineral measurements for said vertebra; 2) for receiving and reviewing said second matrix of data elements to identify at least one pair of fiducial points of said vertebra and to calculate anterior, medial and posterior heights of said vertebra using said fiducial points; a display means (22) serving for outputting from said digital computer said bone mineral measurements and said heights."

Claim 2 to 8 are dependent on claim 1.

V. The appellant argued as follows:

D1 did not disclose the calculation of anterior, medial and posterior heights of the vertebra, so that if the teachings of D1 and D2 were to be combined, there would still remain a feature not present in the resulting apparatus. The claimed invention improved the diagnostic use of the bone mineral density measurements by providing correlated bone height data. There was nothing to suggest that the person skilled in the art would modify either D1 or D2 to provide the advantages.

Reasons for the Decision

1. The appeal is admissible.

2. *Amendments*

2.1 Article 123(2) EPC

Claim 1 on file differs from claim 1 of the application as originally filed essentially in that the claim now specifies that the first and second angles in original claim 1 correspond to the anterior/posterior direction and the lateral direction, respectively, which is clearly based on the original disclosure. Moreover, the claim specifies that the computer calculates the anterior, medial and posterior heights of said vertebra, which is supported by original claim 2.

The dependent claims 2 to 8 correspond to original dependent claims 2 to 8. The description has been amended for consistency with the claims and to acknowledge relevant prior art.

The application meets the requirements of Article 123(2) EPC, accordingly.

2.2 Clarity

During the examination procedure the applicant had introduced terminology into claim 1 which the examining division found objectionable. This terminology has been removed and there is no further objection to the claims on this ground.

3. *The application*

3.1 Prior art digital bone densitometry devices were used to generate values of bone character, such as bone mineral content (BMC) or bone mineral density (BMD). Such information about bone character particularly in the spine is relied on to diagnose and treat bone depletive disorders such as osteoporosis, for which however, bone density measurements alone are not definitive for diagnosis. The clinician must also look for evidence of spinal fracture, which is apparently not easy to define, but D5 suggests as a minimum criterion a decrease in the anterior, medial, or posterior vertebral height of 20% or more (page 183, left column, second paragraph). This document also defines osteoporosis as a decrease in bone density associated with a substantially increased risk of fracture (page 182, right column, last paragraph).

Vertebral morphometry for diagnosing fractures employing analog radiological imaging techniques was known in the prior art, which techniques have been computerized but which rely on manually selecting points of measurement from radiographs, as for example described in D3 (see the introduction) and D6 (see the abstract). Therefore, in diagnosing or treating osteoporosis two relatively expensive medical devices are used, a bone densitometer and an x-ray imaging device. Moreover, morphometric techniques which rely on analog radiography are complicated by an image magnification problem as discussed in column 2, line 33 onwards of the application (see the A1 document).

3.2 Accordingly, the problem to be solved is to provide an apparatus for automatically analysing bone utilizing techniques of densitometry, which will permit the determination of BMC and BMD and in addition will analyse vertebral morphology for use in diagnosis of certain conditions of vertebral deterioration including osteoporosis. Morphometric determinations improve the diagnostic interpretation of the BMD measurements which will tend to be increased by bone compaction when a vertebra is fractured.

In this respect the statement of problem set out in point 2.3 of the communication of the examining division dated 5 September 2000 is not correct since it does not adequately reflect the actual achievement of the claimed device over the prior art.

3.3 The solution is defined in claim 1 of the application, and comprises a digital x-ray bone densitometer for projection scanning of the vertebra to obtain information about the character of a vertebra derived from a first and a second matrix of discrete data elements obtained respectively by positioning a radiation source to perform an anterior/posterior scan and a lateral scan, and a digital computer for receiving and analysing the first matrix of data elements to determine bone mineral measurements for said vertebra, and for receiving and reviewing said second matrix of data elements to identify at least one pair of fiducial points of said vertebra and to calculate anterior, medial and posterior heights of said vertebra using said fiducial points.

Thus a single x-ray bone densitometer is used. Moreover, together with the means for positioning, the apparatus enables the vertebrae to be scanned successively in the anterior/posterior direction and in the lateral direction, which decreases the risk of the patient moving significantly between the two scans.

The calculated values of BMD for various points in the anterior/posterior scan can be correlated with the corresponding points in the lateral scan to improve the interpretation and accuracy of vertebral BMD measurements by providing morphometric information about the vertebra being studied.

4. *Novelty*

Neither of D1 and D2, the principal documents relied upon by the examining division, discloses the use of a computer for receiving a matrix of discrete data elements and automatically identifying at least one pair of fiducial points of said vertebra and for calculating the anterior, medial and posterior heights of said vertebra using said fiducial points. For this reason alone the densitometer of claim 1 is novel over the devices of these documents.

5. *Inventive step*

5.1 The closest prior art Document D1 describes a digital x-ray bone densitometer for projection scanning of the vertebra of an animal or human to obtain information about the character of a vertebra being derived from a first matrix of discrete data elements each having a value wherein each said data element corresponds to a

defined location in said vertebra, and wherein the value of each data element is related to a physical characteristic of the material of the vertebra, the densitometer comprising a means (21) for positioning a radiation source (1) and a detector (5) in opposed relationship about a vertebra for directing radiation along an axis in the anterior/posterior direction through the vertebra and detecting its attenuation to produce the first matrix of data elements, a digital computer (13) for receiving and analysing said first matrix of data elements to determine bone mineral measurements for said vertebra, and a display means serving for outputting from said digital computer said bone mineral measurements.

Although document D1 mentions the measurement of the area of the bone (column 10, lines 13 to 29), this is not per se a disclosure of a morphometric measurement of the vertebrae since the measurement of area is for calculating the area averaged bone mineral density, the area value itself is not used for any purpose such as estimating the compaction of a vertebra as an indication that it is fractured.

5.2 The bone densitometer of claim 1 of the application includes the following further features:

(i) a positioning means for rotating the axis between the anterior/posterior direction and the lateral direction about said vertebra so that said first matrix of discrete data elements is acquired at the first position and a second matrix of discrete data elements is acquired at the second position; and

(ii) means for receiving and reviewing said second matrix of data elements to identify at least one pair of fiducial points of said vertebra and to calculate anterior, medial and posterior heights of said vertebra using said fiducial points.

As stated above, these features enable an anterior scan of the vertebrae to be followed by a lateral scan so that the bone mineral measurements may be correlated with the morphometric determinations without the patient moving significantly between the two scans.

5.3 The question to be resolved, therefore, is whether the prior art would incite the person skilled in the art to modify the apparatus of D1 to include these features.

5.4 As acknowledged in the application (column 1, lines 23 to 27) it was known that in the case of osteoporosis, bone density measurements alone are not definitive for diagnosis and the clinician must also look for evidence of spinal fracture. In this connection D3 investigates the definitions of vertebral fracture and D6 studies the possibilities of radiographic digitisation for determining vertebral dimensions in assessing vertebral fractures. In these cases, however, a radiograph of the spine is taken in the lateral direction, and the radiographs are then used for determining vertebral dimensions. In D5 also studies are made on spinal radiographs (page 183, left column, second complete paragraph).

Although it may reasonably be assumed that the person skilled in the art would seek to automate the

measurement of vertebral dimensions, the prior art consistently teaches to make the measurements on the radiographs and not on the vertebra itself, so that any automation procedure would concentrate on automation of the measurement of the radiographic image. There is no suggestion in the prior art of dispensing with the second apparatus (the first being the apparatus for measuring bone density) for making a radiograph of the vertebra and, instead, obtaining data from a lateral scan on the vertebra itself.

5.5 The impugned decision argues that D1 discloses making morphological measurements. As stated in point 5.1 above, this document is not considered to do this. Moreover, claim 1 of the application requires these measurements to be the anterior, medial and posterior heights of said vertebra, whose purpose is to assess if there is any compaction of the vertebra (column 3, lines 50 to 54). D1 mentions only the measurement of the area of the vertebrae and is silent as to the anterior, medial and posterior heights of said vertebra.

5.6 Document D2 describes only the measurement of bone densities. The apparatus makes multidirectional measurement of human bone densities, for which a positioning means is provided for rotating the scanning beam axis between the anterior/posterior position and the lateral position about said vertebra. However, the lateral scan is performed in order to observe extra-osseous calcification in tissue overlying the lumbar spine, which cannot be distinguished from bone in the anterior/posterior projection (D2, page 4, last two paragraphs) and which may interfere with accurate bone density measurements in the anterior/posterior

projection. There is no suggestion that the lateral projection may be used to calculate the anterior, medial and posterior heights of said vertebra, or that these calculations may be used to increase the accuracy of the bone mineral measurements.

If the person skilled in the art were to be further interested in bone morphology in the process of D2, the prior art teaches that he should add a radiograph apparatus. As stated above, in order to measure the anterior, medial and posterior heights of vertabrae, the prior art consistently teaches the evaluation of these parameters via radiographs of the spine, which, in a method of digital bone densitometry, involves the successive use of different apparatus, namely a digital x-ray bone densitometer and an X-ray apparatus in series. There is no incentive in the prior art for using the same apparatus as used for measuring bone density also for investigation the bone morphology.

5.7 Therefore, the prior art gives no incentive for refining the apparatus of D1 so as to enable it to perform a lateral scan in addition to the anterior/posterior scan disclosed in D1 and to compute the anterior, medial and posterior heights of the vertebrae. For this reason the densitometer of claim 1 of the application involves an inventive step.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the first instance with the order to grant a patent on the basis of the following documents:

   – Description pages 1 to 3 and 5 to 32 as originally filed

   – Description page 4 as filed with the letter dated 31 October 2000

   – Description pages 4a and 4b as filed with the telefax dated 15 December 2004

   – Claims 1 to 8 filed as filed with the telefax dated 15 December 2004

   – Figures 1 to 11 as originally filed.

The Registrar: The Chairman

V. Commare T. K. H. Kriner